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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,231	03/02/2004	Kyoko Kojima	HITA.0519	9839

7590 10/16/2006

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,231	KOJIMA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 4-8,11,12 and 18-20 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3,9,10 and 13-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on July 31, 2006 is acknowledged.

Information Disclosure Statement

2. In the IDS filed August 25, 2004, it is noted that only the abstracts of the patents were filed. No copies of the references were filed. The information disclosure statement filed August 25, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 9, 13, 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Colpan et al (U.S. Patent 6,383,393).

Colpan teaches a method for isolating and purifying nucleic acids (see abstract), which comprises:

(a) providing a mixed solution containing the nucleic acids, protease, chaotropic salts, and at least one organic solvent (see columns 9, example 7, where the DNA from blood is mixed with salts such as GuHCl and organic solvents such as 5%-100% Triton (see line 17) and ;

(b) adsorbing the nucleic acids on an adsorption support (see column 9, lines 30-35, where the DNA is adsorbed onto the porous matrix);

(c) washing the support adsorbed with the nucleic acids with a washing buffer that comprises ethanol (see column 9, lines 33-37, which teaches washing with ethanol);

(d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (see column 9, lines 40-42, which teaches elution),

wherein said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone (See column 9, line 17, where Triton is used. Triton is a compound which comprises 2 to 10 carbon atoms and is a aliphatic ether as shown by the attached page 1031 of the 1996 Sigma catalog).

Triton is an aliphatic ether (see Sigma catalog, page 1031).

With regard to claims 13, 14 and 16, Colpan teaches the use of a column (see column 7) and moving the solution with pressure (see column 9, line 32) or sucking forces (see column 7, line 50).

Double Patenting

5. Claims 1-3, 9-10 and 13-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,905,825 in view of Colpan et al (U.S. Patent 6,383,393).

Claims 1-9 of U.S. Patent No. 6,905,825 teach a method for isolating and purifying nucleic acids, which comprises: providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent; adsorbing the nucleic acids on an adsorption support; washing the support adsorbed with the nucleic acids with a washing buffer; desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids, wherein said organic solvent includes at least one of ethylene glycol dimethyl ether, ethylene glycol diethyl ether, propylene glycol dimethyl ether, propylene glycol diethyl ether, diethylene glycol dimethyl ether, diethylene glycol diethyl ether, tetrahydrofuran, 1,4-dioxane, propylene glycol monomethyl ether acetate, ethyl lactate, hydroxyacetone, acetone, and methyl ethyl ketone.

2. The method for isolating and purifying nucleic acids as claimed in claim 1, wherein the concentration of the organic solvent in said mixed solution is not more than 50% by volume.

3. The method for isolating and purifying nucleic acids as claimed in claim 2, wherein the concentration of the organic solvents in said mixed solution is 5% to 50% by volume.

4. The method for isolating and purifying nucleic acids as claimed in claim 1, wherein said mixed solution contains a surfactant at no more than 50% by volume.

5. The method for isolating and purifying nucleic acids as claimed in claim 4, wherein said mixed solution contains a surfactant at 5% to 50% by volume.

6. The method for isolating and purifying nucleic acids as claimed in claim 1, wherein said mixed solution contains a defoaming agent at 0.2% to 2.5% by volume.

7. The method for isolating and purifying nucleic acids as claimed in claim 1, further comprises: providing a column with a bottom; placing the support above the bottom; causing the mixed solution to pass one-way through the support to the bottom by a sucking force.

8. The method for isolating and purifying nucleic acids as claimed in claim 7, whereby the causing step, the mixed solution also passes through the support the other way by an opposite sucking force.

9. The method for isolating and purifying nucleic acids as claimed in claim 8, whereby the causing step, the mixed solution passes through the support a number of times to enhance adsorption efficiency.

Claims 1-9 of U.S. Patent No. 6,905,825 do not teach teh use of a protease in the isolation mixture.

Colpan teaches a method for isolating and purifying nucleic acids (see abstract), which comprises:

(a) providing a mixed solution containing the nucleic acids, protease, chaotropic salts, and at least one organic solvent (see columns 9, example 7, where the DNA from blood is mixed with salts such as GuHCl and organic solvents such as 5%-100% Triton (see line 17) and ;

(b) adsorbing the nucleic acids on an adsorption support (see column 9, lines 30-35, where the DNA is adsorbed onto the porous matrix);

(c) washing the support adsorbed with the nucleic acids with a washing buffer that comprises ethanol (see column 9, lines 33-37, which teaches washing with ethanol);

(d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (see column 9, lines 40-42, which teaches elution),

wherein said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone (See column 9, line 17, where Triton is used. Triton is a compound which comprises 2 to 10 carbon atoms and is a aliphatic ether as shown by the attached page 1031 of the 1996 Sigma catalog).

Triton is an aliphatic ether (see Sigma catalog, page 1031).

With regard to claims 13, 14 and 16, Colpan teaches the use of a column (see column 7) and moving the solution with pressure (see column 9, line 32) or sucking forces (see column 7, line 50).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the purification method of Claims 1-9 of U.S. Patent No. 6,905,825 by using a protease such as that taught by Colpan since Colpan teaches "In this step, efficient lysis of all eukaryotic and/or prokaryotic cells and/or viruses (with concomitant inactivation of infective pathogens) and denaturing and enzymatic degrading of proteins (with concomitant removal of the proteins bound to the nucleic acids) are taking place simultaneously. (see example 7, column 9, lines 20-25)." An ordinary practitioner would have been motivated to add the protease of Colpan to the purification method of Claims 1-9 of U.S. Patent No. 6,905,825 in order to remove proteins bound to the nucleic acids by the enzymatic degradation of the proteins. An ordinary practitioner would have recognized that this would improve the purification quality and amount of the nucleic acid and promote efficient lysis as motivated by Colpan.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
9/3/06